

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 50-782

CHEMISTRY REVIEW(S)

DIVISION OF TOPICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 50-782

CHEM. REVIEW #: 1

REVIEW DATE: 25-NOV-00

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	27-JAN-00	28-JAN-00	18-APR-00
AMENDMENT/BC	28-APR-00	01-MAY-00	17-MAY-00
AMENDMENT/BC	18-SEPT-00	19-SEPT-00	20-SEPT-00
AMENDMENT/BC	31-OCT-00	01-NOV-00	08-NOV-00
AMENDMENT/BC*	17-NOV-00	17-NOV-00	17-NOV-00
AMENDMENT/BC*	21-NOV-00	21-NOV-00	22-NOV-00
AMENDMENT/BC*	21-NOV-00	21-NOV-00	22-NOV-00
AMENDMENT/BC*	22-NOV-00	22-NOV-00	22-NOV-00

* Faxed

NAME & ADDRESS OF APPLICANT:

Clindagel, LLC
 4189 Chaparral Court
 Santa Rosa, CA 95409

US Representative:

Robert J. McCormack, Ph.D.
 Vice President, U.S. Regulatory Affairs
 Target Research Associates
 554 Central Ave
 New Providence, NJ 07974
 (908) 464-7500

DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN:
Code Names/#s:
Chemical Type
Therapeutic Class:

Clindagel
 Clindamycin Phosphate

 3 S
 Antibiotic

Patent Status:

None

PHARMACOLOGICAL CATEGORY/INDICATION:

Acne vulgaris

DOSAGE FORM:

Gel

STRENGTHS:

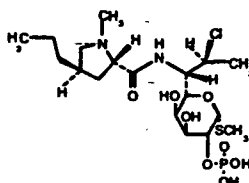
Clindamycin phosphate 1%

ROUTE OF ADMINISTRATION:

Topical

DISPENSED:☒ Rx ☐ OTCCHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT, CAS NUMBER:

- Methyl-7-chloro-6,7,8-trideoxy-6-(1-methyl-4*trans*-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo- α -D-galacto-octopyranoside 2-(dihydrogen phosphate)
- 7(S)-Chloro-7-deoxylincomycin



NDA 50-782
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page 2 of 24

MOLECULAR FORMULA: $C_{18}H_{34}ClN_2O_8P_8S$

MOLECULAR WEIGHT: —

CAS NUMBER: 24729-96-2

SUPPORTING DOCUMENTS:

♦ IND 56,487 (same drug product, same indication, same sponsor).

RELATED DOCUMENTS:

None

CONSULTS:

None

REMARKS/COMMENTS:

This NDA was originally submitted as — The number was later administratively changed to the current NDA number.

The major issue is the applicant's use of an — for which four justifications are offered, none of which are satisfactory (see page 6 for details). The applicant was therefore requested: —

During a Telecon on November 15, 2000, the applicant requested that they be allowed to use the manufacture of the commercial batches during the first year as a basis of whether using the — justified. The applicant stated that an evaluation would be made by the end of one year and that if no manufacturing losses that would justify the — are observed, the applicant would submit a supplement

(— The agency concurred, and requested that the applicant make the commitment in writing, which was provided on November 17, 2000. Other issues, including labeling issues, are covered in the review. There are no CMC hold issues.

NDA 50-782
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page 3 of 24

CONCLUSIONS & RECOMMENDATIONS:

The application is **APPROVED** for manufacturing and controls under section 505 of the Act

Saleh A. Turujman, Ph.D.
Review Chemist

cc: Orig. NDA 50-782
HFD-540/Division File
HFD-540/SA Turujman/11/22/00
HFD-540/MO/PHuene
HFD-540/Pharm/PBrown
HFD-540/Micro/PCooney
HFD-540/PM/IKumar
HFD-540/ChemTmLdr/WHDeCamp
HFD-540/BioPharm/AAdebowale

In DFS

C:\MY DOCUMENTS\TURUJMAN\REVIEWS\NDA\50782\50782 REV #1 NOV 22 2000.DOC

**APPEARS THIS WAY
ON ORIGINAL**

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**THIS SECTION
WAS
DETERMINED
NOT
TO BE
RELEASABLE**

21 pages

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ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 21230/000

Priority: 3S

Org Code: 540

Stamp: 27-JAN-2000 Regulatory Due: 27-NOV-2000

Action Goal:

District Goal: 28-SEP-2000

Applicant: CLINDAGEL
4189 CHAPARRAL CT
SANTA ROSA, CA 95409Brand Name: CLINDAGEL (CLINDAMYCIN
PHOSPHATE TOPICAL

Established Name:

Generic Name: CLINDAMYCIN PHOSPHATE
TOPICAL GEL

Dosage Form: GEL (GEL)

Strength: 1%

FDA Contacts: I. KUMAR (HFD-540)
J. VIDRA (HFD-540)
W. DECAMP II (HFD-540)301-827-2072 , Project Manager
301-827-2065 , Review Chemist
301-827-2041 , Team Leader

Overall Recommendation:

Establishment:

DMF No:

AADA No:

Profile: OIN OAI Status: NONE
Last Milestone: SUBMITTED TO OC
Milestone Date: 09-FEB-2000

Responsibilities:

Establishment:

DMF No:

AADA No:

Profile: OIN OAI Status: NONE
Last Milestone: SUBMITTED TO OC
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Responsibilities:

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Establishment:

DMF No:

AADA No:

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OAI Status: NONE

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Last Milestone: SUBMITTED TO OC

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